Exhibit 16

#5

Patent
Attorney's Docket No. LSCP1022MAH

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of
Inventor: Russell Pon
Application No.: 08/086,014
Filed: July 2, 1993
For: PROBE HAVING OPTICAL FIBER FOR LATERALLY DIRECTING LASER BEAM

Group Art Unit: 2501
Examiner: Unassigned

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8 - FIRST CLASS MAIL
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Cecilia A. Maida (Signature)
By: Cecilia A. Maida (Type Name)
Signature Date: 10/22/93

10/19/93
2571

INFORMATION DISCLOSURE STATEMENT
BEFORE FIRST OFFICE ACTION

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Sir:

Enclosed please find a Form PTO-1449 listing prior art for consideration by the Examiner in the above-identified U.S. patent application, and copies of the cited references. This Information Disclosure Statement if filed prior to the First Office Action, and therefore, no fee is required.

The Examiner's attention is drawn to the translation of Japanese Kokai Patent Application No. 61-219904 invented by Abe, et al. In particular, at page 6, dimensions of the diameter of the fiber conductor are recited as a core size of 400 microns with an outer diameter of the cladding of 650 microns. On first pass, it would appear to describe a system that satisfies the relation in Claim 2, for instance, in the present application in which the outside diameter of the "core cladding layer" is greater than about 1.4 times the outside radius of core. However, in the Japanese reference, the dimensions of the cladding layer are believed to refer to the entire cladding structure, including the so-called primary coating layer 12 and protective coating pipe 13. However, it is the position of the inventor in the present application that

had these numbers referred to the fiber core and the core cladding layer alone as claimed in the present invention, the problem of misdirected energy which the Japanese reference seeks to solve would not have occurred. Therefore, it is believed that this Japanese reference does not teach the present invention.

These dimensions also appear on page 9 of the Japanese Kokoku Patent No. 3-63377 which is enclosed. It is believed that these numbers in the Japanese translations not teach the features described and claimed in the present invention. Indeed, the elaborate techniques used in these references to minimize the damage done by misdirecting energy by the lateral beam directing fiber tips described in those applications establish that they did not use a core cladding layer to core ratio taught by the present invention.

There are a number of other references attached which address the issue of laterally directing a laser beam. However, none are believed to suggest the present invention.

Prosecution of the course of the present application is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. § 1.17 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 08-1405. This paper is submitted in duplicate.

Respectfully submitted,

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SHEET 1 OF 1

INFORMATION DISCLOSURE CITATION	ATTY. DOCKET NO. LSCP1022MAH	SERIAL NO. 08/086,014
	APPLICANT RUSSELL PON	
PTO-1449	FILING DATE 07/02/93	GROUP 2501

U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
PTH	4,273,127	06/81	Auth, et al.	128	303.1	08/80
PTH	4,566,438 ✓	01/86	Liese, et al.	128	6	10/84
PTH	4,620,547	11/86	Boebel	128	754	12/84
PTH	4,669,467 ✓	06/87	Willett, et al.	128	303.1	03/85
PTH	4,740,047	04/88	Abe, et al.	350	96.15	03/86
PTH	4,819,632 ✓	04/89	Davies	128	303.1	05/87
PTH	4,832,979	05/89	Hoshino	427	38	09/87
PTH	4,852,567 ✓	08/89	Sinofsky	128	303.1	01/88
PTH	5,000,752	03/91	Hoskin, et al.	606	9	06/89
PTH	5,041,121	08/91	Wondrazek, et al.	606	128	12/89
PTH	5,093,877	03/92	Aita, et al.	385	34	10/90

FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation Yes	Translation No
PTH	0 163266 A2	05/85	European Patent Office	4	G02B23	X	
	~~31 19322 A1~~	~~5/81~~	~~Germany~~	~~3~~	~~A61B17~~		X
PTH ✓	61-219904	09/86	Japan	4	G02B6/10	X	
PTH ✓	3-63377	09/91	Japan	5	A61B17	X	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

RECEIVED OCT 27 1993 GROUP 2500

EXAMINER	DATE CONSIDERED
PHAN THI HEARTNEY	02/04/1994

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

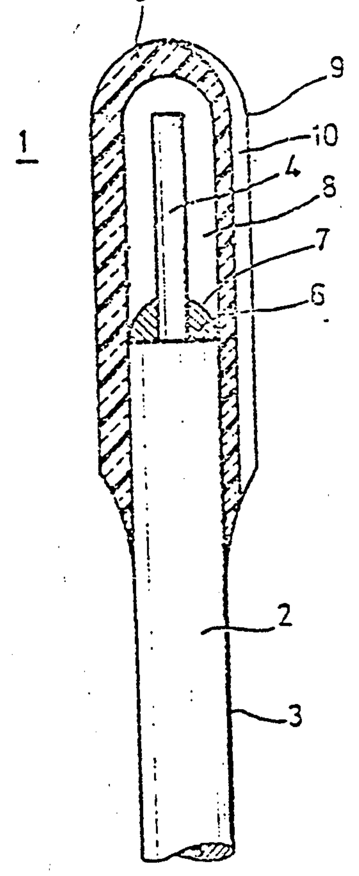
DOC\LSCP1022.002

MESR ☆ S05 B4137 K/05 ☆DE 3119-322
Probe for inducing atrophy of varicose veins - has heat radiating light conductor linked to laser source
MESSERSCHMITT-BOLKOW-BLO 15.05.81-DE-119322
P31 (27.01.83) A61b-17/36
15.05.81 as 119322 (1468MB).

The light conducting probe, using a laser with high infra red content as source, is used for the surgical therapy of varicose veins. Heat transfer is improved by the rough surface of the exposed part of the light conductor.

The roughened end of the light conductor (4) radiates heat through the transparent cap (5). A polished metal dome (6) acts as heat sink and tracer for radiography. (Spp Dwg.No.1/1)

N83-018468 S5-B



Code: 1314-20608

JAPANESE PATENT OFFICE

PATENT JOURNAL

KOKAI PATENT APPLICATION NO. SHO 61[1986]-219904

Int. Cl.[4]:	G 02 B 6/10 27/00 A G1 B 1/00 17/36 H 01 S 3/00
Sequence Nos. for Office Use:	D-7370-2H Q-7529-2H 7916-4C 6791-4C 7113-5F
Application No.:	Sho 60[1985]-61267
Application Date:	March 26, 1985
Publication Date:	September 30, 1986
No. of Inventions:	1 (Total of 8 pages)
Examination Request:	Not requested

LASER BEAM SIDE IRRADIATING FIBER

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[Amendments have been incorporated into the text.]

Claims

1. A type of laser beam side irradiating fiber characterized by the following facts: an inclined surface is formed at the tip of a fiber base conductor made of a core and a cladding with refractive indexes different from each other at an angle in the range of about 35°-40° to the central line of the fiber base conductor; the end portion including the inclined surface is fitted with a transparent cylinder with one of its terminals closed to form an air layer adjacent to the aforementioned inclined surface, so that the inclined surface is used as a total reflection surface for the laser beam side irradiating fiber; the aforementioned transparent cylinder is equipped with at least two coating layers; the transparent cylinder and fiber are connected to each other by a pipe, and the laser beam output surface of the transparent cylinder is coated with an antireflection coating.

2. The laser beam side irradiating fiber described in Claim 1 characterized by the fact that the aforementioned antireflection coating is formed by coating on the plane portion formed on the transparent cylinder.

3. The laser beam side irradiating fiber described in Claim 1 characterized by the fact that the aforementioned connecting pipe encloses almost the entire transparent cylinder which forms the laser beam output opening.

4. The laser beam side irradiating fiber described in Claim 2 characterized by the fact that on the aforementioned transparent cylinder, a total reflection coating is formed on the surface roughly symmetric to the surface on which the aforementioned antireflection coating is formed with respect to the central line.

5. The laser beam side irradiating fiber described in Claim 2 characterized by the fact that for the aforementioned fiber conductor, a third coating layer is arranged on the opening portion with an outer diameter roughly equal to [that of] the transparent cylinder in contact with it.

6. The laser beam side irradiating fiber described in Claim 5 characterized by the fact that the aforementioned connecting pipe is a heat-shrinking tube.

Detailed explanation of the invention

Industrial application field

This invention concerns a type of laser beam side irradiating fiber. More specifically, this invention concerns a type of laser beam side irradiating fiber used for irradiating the laser beam from the side onto the lesion in the lumina of viscera via an endoscope.

Background of the invention

With rapid progress achieved in the laser technology and light transmission fiber technology, the diagnosis and treatment

of lesions, such as tumors, etc., in lumina of viscera by endoscopic irradiation of a laser beam have been actually used in clinical operation. There are several types of fibers used for leading the laser beam endoscopically into the lumina of viscera for irradiation, such as the front radiating fiber which has an output end surface at a right angle to its length direction, and the side irradiating fiber which outputs the laser beam through its side surface [with the laser beam] at right angle [to the length direction]. When the laser beam is to be used to irradiate the lesion in a narrow channel, such as in the esophagus, trachea, intestines, etc., it is desired that the energy irradiated onto the lesion be uniform over the entire lesion. For this purpose, the present applicant proposed in Japanese Patent Application No. Sho 59[1984]-187782 a type of laser beam side irradiating fiber which can irradiate the lesion in the normal direction, that is, in the direction perpendicular to the wall of the channel. In the laser beam side irradiating fiber disclosed in Japanese Patent Application No. Sho 59 [1984]-187782, the output surface is formed as an inclined surface at about 45° to the central line of the fiber base conductor; the aforementioned inclined surface is fitted with a transparent cylinder with one end closed in a shape free of an acute angle; since an air layer is formed on the back of the fiber's output inclined surface, it becomes a total reflection surface so that the laser beam transmitted in the fiber is bent and outputted from the side surface of the fiber. More specifically, the design may be explained with reference to Figure 6. Figure 6 is a cross-sectional view of a conventional laser beam side irradiating fiber. Fiber conductor (11) is a

conventional optical fiber conductor made of a core and a cladding having different refractive indexes. It is a fused silica fiber with a core size of 400 μm and an outer diameter of the cladding layer of 650 μm. Fiber conductor (11) is covered over its entire length with a primary coating layer (12) made of a synthetic resin. Fiber conductor (11) with primary coating layer (12) formed on it is further protected by a flexible protective coating pipe (13), which is used to prevent cracks formed on fiber base conductor (11) and to prevent folding of fiber base conductor (11). This protective coating pipe (13) is preferably made of vinyl type resin material, nylon, teflon, or other synthetic resin material. In order to bend the transmitted laser beam so that it is outputted in a direction at right angle to the length direction of the fiber, the end portion of fiber base conductor (11) is formed as an inclined surface (14) at about 45° to the central line of fiber base conductor (11), and this inclined surface is polished to a smooth optical-quality surface. Primary coating layer (12) and protective coating pipe (13) are peeled off for a length of the tip portion including inclined surface (14) at 45° formed on fiber base conductor (11). For the output end, fiber base conductor (11) with primary coating layer (12) and protective coating pipe (13) peeled off is fitted with a transparent cylinder (15) with a circular cross-section and with one end closed to a hemispherical shape, followed by air-tight sealing using an epoxy type adhesive (16). Inclined surface (14) of fiber base conductor (11) is set appropriately to ensure formation of an air layer (17) between the inner surface of cylinder (15) and inclined surface (14) of fiber base conductor (11) within transparent cylinder (15). A

step portion (18) is formed over the entire circumference of the opening end side of transparent cylinder (15). The fiber base conductor (11) is protected over the entire length by Teflon or other flexible material on the step portion (18). For the purpose of reinforcement, it is bonded to the tip portion of a reinforcing tube (19); or, the tip portion of the reinforcing tube may be heated to expand its inner size and then cooled to shrink for attachment after the [fiber] is inserted. For this reinforcing tube (19), a circular cross-sectional gap (20) is formed over the entire length between its inner periphery and protective coating pipe (13) of fiber base conductor (11). For this purpose, it has a sufficient inner diameter and an external shape almost identical to the external shape of transparent cylinder (15).

On a portion of transparent cylinder (15), a groove (20) connected to said gap (21) is formed when the tip of fiber base conductor (11) and the tip of reinforcing tube (19) are fitted in the opening end of said transparent cylinder (15).

Although the aforementioned laser beam side irradiating fiber is very effective when it used as direct-viewing endoscopic equipment, it nevertheless has the following disadvantages:

First of all, since a thin air layer is formed between the inner wall surface and the outer wall of the fiber base conductor in the length direction of the transparent cylinder, the interface acts as a reflective surface. Consequently, a beam is formed in a direction different from the desired direction, in particular, in the opposite direction (that is, a leakage beam). Since the leakage beam has a high energy, it may unintentionally burn the normal tissue outside the lesion. In order to eliminate

the interface reflection caused by the aforementioned air layer, a very high fitting precision has to be realized by increasing the manufacturing precision of the outer diameter of the fiber base conductor and the inner diameter of the cylinder, so that no air layer is left between these two parts. This is nevertheless undesired for mass production. Even if this can be realized, since the tip has a sharp shape with an angle of 45°, it is rather difficult to insert the fiber base conductor made of, say, fused silica, into the cylinder without hitting the cylinder. Consequently, the cost of assembly operation is boosted.

In addition, other leakage beams may also be generated in addition to the aforementioned leakage beam caused by the aforementioned air layer interface. This leakage beam is axially propagated from the probe. This is because as depending on the transportation mode of the laser beam incident into the fiber, when the incident angle at the total reflection surface becomes smaller than the critical angle, for a certain portion of the incident laser beam, this portion of laser beam is not reflected to the side, and it passes the 45° inclined surface and goes forward. Just like the aforementioned leakage beam caused by reflection from the interface, this leakage beam also may burn the normal tissue outside the lesion.

The third problem of the conventional laser beam side irradiating fiber is related to its damage due to folding during the application process. That is, in the operation mode as endoscopic equipment, the fiber probe is not led to the target portion in the body along a straight line. Instead, in order to trap the lesion within the viewfield of the endoscope, the fiber has to be bent in three dimensions to reach the target portion in

the body along the path for insertion. The leading passage is usually the so-called pincer channel, that is, a passage for leading operating pincers and with inner diameter of 2-3 mm. For the present endoscope, the bending radius of this pincer channel is rather small. In this case, when the fiber is to pass through a bend, an external force in a direction crossing the axial direction is applied to the tip portion of the fiber. As can be seen from Figure 6, in this state, a large external force is applied on the cylinder and its vicinity in a direction different from the axial direction, a shear force is generated at the boundary between the portion of the fiber base conductor covered with the rigid cylinder and the portion covered by the flexible coating layer and coating tube. In some cases, the cylinder may fall off and be left in the body. This is extremely dangerous.

There are also problems related to the application as an endoscope, or, in particular, as a direct-viewing endoscope. That is, in this case, it is necessary to confirm that both the aiming beam and the laser beam for treatment are within the view field of the endoscope. Consequently, the tip of the fiber probe has to protrude over the tip of the direct-viewing endoscope. As the amount of protrusion is increased, it becomes more difficult to make a fine adjustment of the laser beam irradiating direction by adjusting the degree of bending of the tip of the endoscope. In addition, the bending operation by adjusting the degree of bending of the tip portion has to be carried out with great care. In particular, care should be paid to avoid the danger caused by contact between the tip of the fiber probe and the bent narrow channels. This contact causes accumulation of mucosa, blood, or other foreign matter on the fiber probe, in

particular, on the cylinder. Deposition of the foreign matter causes absorption of the laser beam, which may lead to heating and burning of the cylinder.

Purpose of the invention

The purpose of this invention is to solve the aforementioned problems of the conventional methods of laser beam side irradiating fiber by providing a new type of laser beam side irradiating fiber characterized by the fact that there is no harmful leakage beam, and there is no damage caused by folding.

Another purpose of this invention is to provide a type of laser beam side irradiating fiber characterized by the fact that the protrusion amount is small at the tip portion when it is used together with an endoscope.

Summary of the invention

This invention provides a type of laser beam side irradiating fiber characterized by the following facts: an inclined surface is formed at the tip of a fiber base conductor made of a core and a cladding with refractive indexes different from each other at an angle in the range of about 35°-40° to the central line of the fiber base conductor; the end portion including the inclined surface is fitted with a transparent cylinder with one of its terminals closed by a portion having no acute angle, or preferably by a hemispherical surface and with its inner diameter sufficiently large with respect to the outer diameter of the fiber base conductor to form an air layer

adjacent to the aforementioned inclined surface; an antireflection coating is formed on one side of the outer surface of the cylinder, while a total reflection film is coated on the other side of the outer surface.

Furthermore, according to this invention, the laser beam side irradiating fiber has a configuration in which the transparent cylinder is fitted with a portion of it overlapped with the protective coating of the fiber conductor.

Also, according to this invention, for the laser beam side irradiating fiber, a plane parallel to the central axial line is formed on a portion of the transparent cylinder, and at least an antireflection coating is coated on the aforementioned plane.

In the aforementioned configuration of the laser beam side irradiating fiber, its output end is made of an inclined surface at an angle of 35-40° and is used as a total reflection surface. In addition, an antireflection coating is formed on a portion of the side surface of the transparent cylinder covering the aforementioned total reflection surface, and a total reflection film is coated on the opposite side of the outer surface. Consequently, the harmful leakage of laser beam can be prevented. Since the aforementioned antireflection coating and total reflection film are coated on the portions of the cylinder processed to planes, the functions of the films can be displayed reliably.

In addition, as the transparent cylinder is fitted with the protective coating portion of the fiber base conductor, the external force applied on the cylinder can be absorbed easily by the protective coating portion. Consequently, damage to the tip of the fiber base conductor caused by folding can be prevented.

Application examples

In the following, the laser beam side irradiating fiber in this invention will be explained in more detail with reference to application examples illustrated by the annexed figures.

Figures 1-4 show an application example of the laser beam side irradiating fiber of this invention. Figure 1 is a schematic diagram. (1) represents a laser beam side irradiating fiber (referred to as irradiating probe hereinafter), with the laser beam emitted from a laser device not shown in the figure transmitted to its exit end. The irradiating probe is made of a core fiber (11) and a cladding layer (see Figure 2) as in the conventional scheme. For example, it may be a fused silica fiber in which the laser beam makes repeated reflection during transmission within the probe. Although this irradiating probe (1) may be used in its original form, it may also be used via an endoscope when treatment is to be performed on lumina of viscera without celiotomy. That is, after observation head (2A) of a conventional endoscope (2) is inserted into the desired channel, irradiating probe (1) is led into the channel through the inserting passage for pincers, etc. arranged for the endoscope (as indicated by insertion opening (2B)). For output end (1A) of irradiating probe (1), the radiation direction can be adjusted together with the observation field of view by means of a bending knob (2C) of the endoscope as well as observation head (2A) of endoscope (2).

The configuration of radiating end (1A) of irradiating probe (1) can be explained with reference to Figures 2(A), (B), (C) and Figure 3.

Fiber conductor (11) used as the laser beam side irradiating fiber in this invention is made of a core and a cladding having different refractive indexes as in the conventional design. The optical fiber conductor may be made of either glass or plastic material. In the case of this application example, the fused silica fiber base conductor is made of a core with a size of 400 μm and a cladding layer with an outer diameter of 650 μm. These diameters may be selected according to the specific application purpose. As shown in the figure, over the entire length of the fiber base conductor, irradiating probe (1) is covered by three coating layers. The first coating layer (12) is known as a primary coating layer, such as a coating layer made of silicon. The second coating layer (13) is a coating tube, such as a nylon tube. The third coating layer (16) is a coating tube, such as a teflon tube. First and second coating layers (12), (13) are the same as those in the conventional optical fibers. They are not used directly for transmitting light. Instead, they are merely used for preventing generation of cracks on the fiber base conductor, and for preventing damage to fiber base conductor (11) by folding. Third coating layer (16) is a portion of the special features of this invention. It will be explained in detail later.

The output face of fiber base conductor (11) is an optically smooth inclined surface (14) at an angle of about 35-40° with respect to the central line of fiber base conductor (11). For fiber base conductor (11) with inclined surface (14) formed at its tip, over a length including its tip, first through third coating layers (12), (13), and (16) are removed by peeling. In particular, the third coating layer is peeled for a portion with

an even larger length. With the exposed portion of fiber base conductor (11) included, the exposed portion of second coating layer (13) is fitted with a hollow cylinder (15) with a transparent circular cross-section and with one end closed to a hemispherical shape. The opening end of hollow cylinder (15) is in close contact with the tip of third coating layer (16). It is preferred that an adhesive be used to make the contact portion between the coating layer and the cylinder body. As can be seen from Figure 2 (C), on cylinder body (15), nearly parallel plane portions (15A) and (15B) are formed opposite to each other. Consequently, although the outer diameter of coating (16) is nearly identical to that of cylinder (15), there is still a significant step with cylinder (15) at said plane portions (15A) and (15B).

Cylinder (15) and third coating layer (16) are fitted with a heat-shrinking tube (17), which fastens and protects them by means of the heat-shrinking effect. Although there is a step at the joint portion with plane portions (15A), (15B) of cylinder (15), these portions are also tightly fastened due to the shrinking effect of heat-shrinking tube (17).

An antireflection coating is formed on planar portion (15A) of cylinder (15), and a total reflection film is formed on plane portion (15B).

For the irradiating probe (1) of this invention with the aforementioned configuration, when a laser beam is emitted from a laser device not shown in the figure, the laser beam transmits the fiber conductor (11) by repetitive total reflection in the conventional form, it is then totally reflected at inclined surface (14), passes through transparent cylinder (15) containing

plane portion (15A), so that the laser beam is projected forward in the direction of 60-75°. Since an antireflection coating is applied on plane (15A), the generation of a reflected beam can be prevented. On the other hand,the reflected beam from the other interface cannot pass through plane (15B) since a total reflection film is applied to this plane.

For irradiating probe (1) with the aforementioned configuration, the generation of undesired leakage beams due to reflection at the interface with the air layer present in the cylinder and their output in the undesired direction can be prevented by the total reflection film coated on plane portion (15B). Even when the leakage beam cannot be completely prevented, it can at least be alleviated to a level at which no thermal destruction takes place for the normal portion in the medical sense. Consequently, an air layer between the inner surface of cylinder (15) and the outer surface of fiber conductor (11) is allowed to be left there.

This feature significantly facilitates the operation for installing cylinder (15) on the fiber. That is, in this case, there is no need to make a strict control on the precision of fitting between cylinder (15) and the fiber. In addition, as there is a difference in dimensions between the aforementioned inner diameter and outer diameter corresponding to the thickness of the first and second coating layers, the insertion of fiber base conductor (11) can be performed easily without the tip bumping on cylinder (15). This improves the operation efficiency.

For the bonding portion between cylinder (15) and fiber, instead of a direct bonding between cylinder (15) and fiber base

conductor (11), bonding is performed via first and second coating layers (12), (13). Consequently, the conventional state in which both the rigid portion and the flexible portion are arranged on a same plane (the plane at right angle to the central line) can now be avoided. Hence, even when a large external force is applied to cylinder (15), it does not become a shear force applied directly on the fiber base conductor. Consequently, the problem of damage to the tip of fiber base conductor (11) by folding in the conventional design can now be avoided.

Since the irradiating direction is forward with angle in the range of 60-75° with respect to the central line of the fiber wire (11), as can be seen from Figure 4, the amount of protrusion from the tip of the endoscope is shorter than that in the conventional case of 90° side irradiation (see Figure 4(A)). In this case, although for certain shapes of lesion (represented by o), a shadow portion may be present for the irradiating beam, the same function as in the conventional case of 90° side irradiation can still be realized by inserting the endoscope deeper and then bending observation head (2A) of the endoscope a little. In Figure 4, W represents the wall of the channel for treatment.

In the aforementioned application example, planes (15A) and (15B) are formed respectively on the side of the output side of cylinder (15) and the opposite side. However, in the case when the leakage beam is small, plane (15A) may be omitted, and the total reflection film may be coated directly on the curved surface, or the total reflection film may even be omitted completely. On the other hand, for the output side of the irradiating beam, although plane (15A) may be omitted in certain cases, the total reflection film is nevertheless a must. As far

as the properties of the coating film are concerned, although a uniform film may be formed on a curved surface, usually, for the film coated on the curved surface by means of the evaporation method, the film thickness tends to decrease from the center to the sides. Consequently, the portion with the desired film properties is limited only to a very narrow portion near the center. Consequently, in the case when plane (15A) is formed, the film over the entire plane range can meet the design requirement on the film.

Plane (15A) formed for the aforementioned purpose is beneficial for specifying the relative positions of fiber base conductor (11) and inclined surface (14) in the assembly operation of the irradiating probe. That is, for the cylinder with a length of about 9 mm and an outer diameter of about 2 mm with a coating film but without a plane portion, it is difficult to make a visual determination, and it is thus very difficult to have the coating film portion in alignment with the output direction of the fiber base conductor. On the other hand, when a plane is formed on it, it can be seen by a glance, and the assembly operation can be carried out easily.

Figure 5 shows another application example of this invention.

This application example differs from the first application example only with respect to the shape of the heat-shrinking tube. The other features are identical to those in the first application example.

As shown in Figure 5, heat-shrinking tube (27) has a circular opening (28) corresponding to the beam exit portion of cylinder (15), and it covers the entire body of cylinder (15).

In this application example for the action of heat-shrinking tube (27), when cylinder (15) is damaged for certain reasons, no fragments will be left in heat-shrinking tube (27), and it can be removed from the body easily.

Effects of the invention

The laser beam side irradiating fiber of this invention can be led into the lumina of viscera via an endoscope, the lesion can be irradiated almost with normal incidence of the laser beam; no damage due to folding takes place when it is inserted into very fine endoscopic leading passages with a small tolerable radius of curvature, and the leakage beams can be reduced to a level on which the normal tissue is not damaged.

Brief explanation of the figures

Figure 1 is a schematic diagram illustrating the application state of the laser beam side irradiating fiber of this invention. Figure 2 (A), (B), (C) are cross-sectional views illustrating an application example of the laser beam side irradiating fiber in this invention. Figure 3 shows the appearance of the laser beam side irradiating fiber in Figure 2. Figures 4 (A), (B) compare the tip protrusion length between the conventional laser beam side irradiating fiber and the laser beam side irradiating fiber in this invention. Figure 5 shows the appearance of another application example of the laser beam side irradiating fiber of this invention. Figure 6 is a cross-sectional view of a conventional laser beam side irradiating fiber.

1, irradiating probe
2. endoscope
11, fiber base conductor
12,13,16, coating layers
14, inclined surface
15, transparent cylinder
17,27, connecting pipe
28, irradiating opening

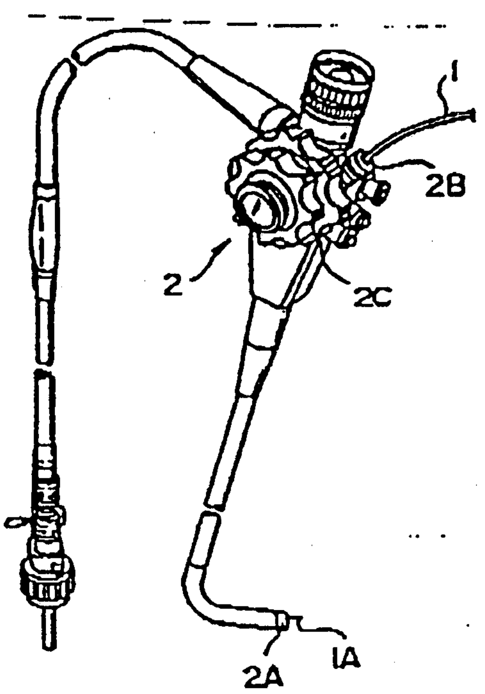

Figure 1.

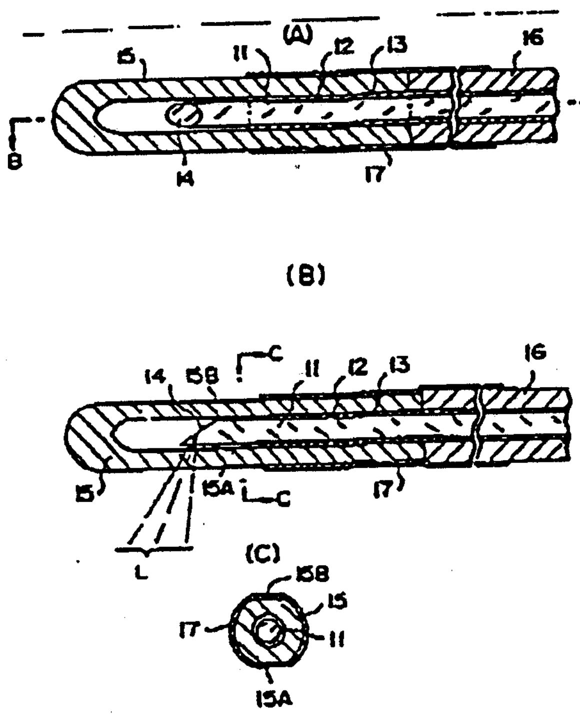

Figure 2.

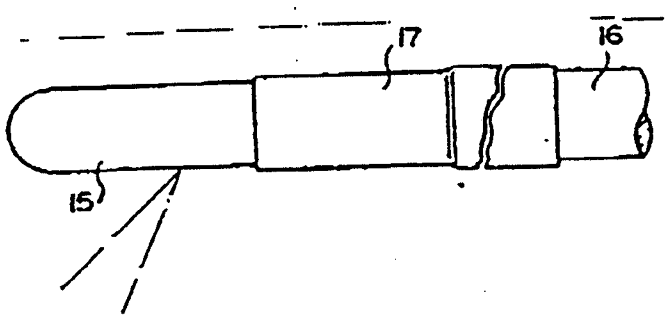

Figure 3.

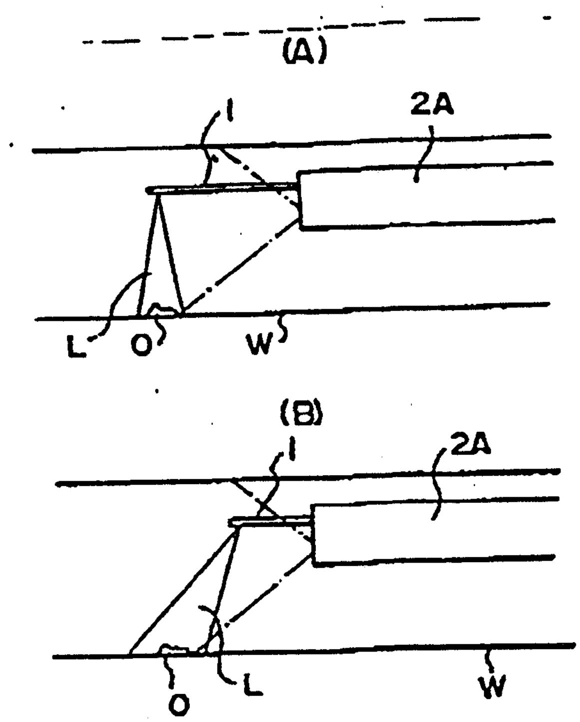

Figure 4.

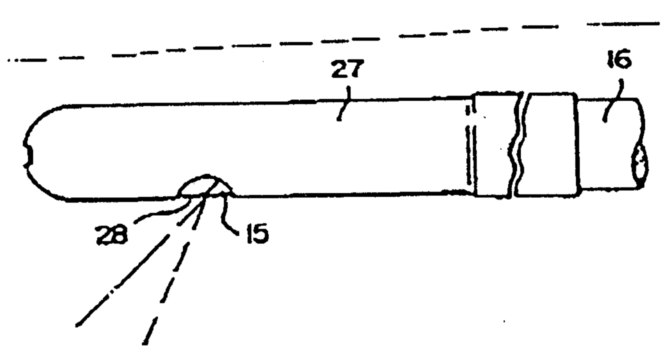

Figure 5.

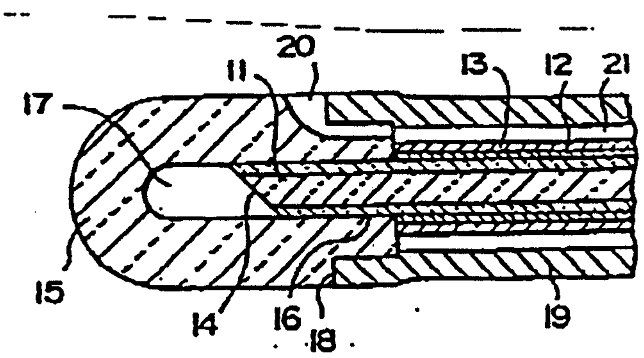

Figure 6.

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JAPANESE PATENT OFFICE

PATENT JOURNAL

KOKOKU PATENT NO. HEI 3[1991]-63377

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Application No.:	Sho 59[1984]-187782
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Kokai Date:	April 2, 1986
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LASER BEAM SIDE IRRADIATING FIBER

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References Cited:

Japanese Kokai Patent Application No. Sho 60[1985]-108804
Japanese Kokai Patent Application No. Sho 60[1985]-53161
Japanese Kokai Patent Application No. Sho 59[1984]-120148

[There are no amendments to this patent.]

Claims

1. A type of laser beam side irradiating fiber characterized by the following facts: in this laser beam side irradiating fiber, the laser beam transmitted in the fiber conductor made of a core and a cladding having different refractive indexes has its optic path reflected and bent by about 90° so that the laser beam is output to the side with respect to the length of the fiber;

an inclined surface is formed at the tip of the fiber base at an angle of about 45° with respect to the central line of the fiber; the end portion of the fiber base conductor including the aforementioned inclined surface is fitted with a transparent cylinder with one end closed so that the aforementioned inclined surface is sealed, and an air layer is set adjacent to the inclined surface, and the inclined surface becomes a total reflection surface.

2. The laser beam side irradiating fiber described in Claim 1 characterized by the fact that on the aforementioned transparent cylinder, an air injecting opening is connected to the gap formed by the fiber base conductor and the flexible tube installed on it.

Detailed explanation of the invention

Industrial application field

This invention concerns a type of laser beam side irradiating fiber. More specifically, this invention concerns a type of laser beam side irradiating fiber used for irradiating the laser beam from the side on the lesion portion in lumina of viscera via an endoscope.

Background of the invention

With rapid progress achieved in laser technology and optical fiber technology, the diagnosis and treatment of lesions, such as tumors, etc., in lumina of viscera by endoscopic irradiation via a laser beam have been actually used in clinical operation. Fibers used for irradiating the lesion portion with the laser beam transmitted endoscopically into the lumina of viscera include the direct irradiating type fiber in which the output end surface is at a right angle to the length of the laser beam side irradiating fiber. When the direct irradiating type fiber is used endoscopically, the endoscope's movement is limited within the narrow lumina of viscera, and movement may be not be possible at certain sites. In some cases, although the lesion portion is in the field of view, it is still impossible to irradiate via laser beam. In other cases, since the lesion or its vicinity is deformed, the lesion simply cannot be irradiated. These are disadvantages.

When the laser beam side irradiating fiber is used together with the direct irradiating type endoscope, the laser beam side irradiating fiber is led almost parallel to the optical axis of the object lens of the endoscope; hence, the lesion portion is irradiated in the tangential direction. Consequently, the near portion is irradiated with higher energy, while the remote portion is irradiated with insufficient energy. That is, nonuniform irradiating energy is unavoidable in this case. As the lesion may be deformed, there may be a portion which cannot be irradiated at all. Nonuniform irradiation energy is a serious problem in clinical practice.

A uniform distribution of the irradiating energy can be realized by normal irradiation of the laser beam onto the lesion portion. In this respect, there have been efforts to realize normal incidence irradiation of the lesion portion by means of a so-called oblique-view endoscope or side-view endoscope. However, for both the oblique-view and side-view endoscopes, the observed field of view is much narrower than that of the direct-view endoscope. Consequently, they are not ideal means in consideration of ease of surveying and observing the lesion portion, as well as ease of treatment as the laser beam side irradiating fiber is used. In the case when the side-view type endoscope is used, in order to lead out the irradiating fiber, its tip side has to be bent significantly. With the presently available material of the fiber base conductor, there is a high possibility of damage by folding. If the damaged parts are left in the human body, an extremely dangerous condition for the patient results.

In Japanese Patent Application No. Sho 58[1983]-161585, the present applicant disclosed a type of laser beam side irradiating fiber which makes use of the characteristics and advantages of the direct-view type endoscope in observation via normal incidence irradiation of the lesion in the lumina of viscera. For the laser beam side irradiating fiber proposed in Japanese Patent Application No. Sho 58[1983]-161585, the output end is formed as an inclined surface at about 45° with respect to the central axis of the fiber base conductor; the laser beam transmitted in the fiber has its optical path reflected and bent at about 90° and is output to the side from the side surface of the fiber. In order to increase the reflective efficiency of the inclined reflective surface, a reflective film is coated on the outer surface of the inclined surface. This type of laser beam side irradiating fiber well realizes the initial purpose, namely, irradiation of the inner wall of the luminal organ by the laser beam from the laser beam side irradiating fiber. However, it nevertheless has the following disadvantages for practical applications. For the reflective film coated on the inclined reflective surface at the output end of the fiber base conductor, sufficient reflectivity cannot be realized, and the energy loss is increased. As a result, the reflective film degrades and may even burn. This problem may develop easily as the output energy of the laser beam increases. In this case, the tip portion of the fiber base conductor itself may burn. Since the laser beam irradiating fiber is used in the lumina of viscera, blood or other body fluids may accumulate on the reflective coating layer on the tip portion of the fiber. Accumulation of the foreign

substances further reduces the output energy level at which the fiber tip burns.

On the other hand, for the medical laser beam irradiating fiber, the length should be in the range of 1.5 mm-several meters. It is rather difficult to form a reflective coating layer only on the minute area on the tip of the fiber base conductor with the aforementioned length. For example, the coating process becomes difficult using the vacuum evaporation operation. Also, since the entire fiber base conductor is heated to a high temperature, the primary coating layer may be degraded or damaged, and the fiber base conductor may be easily damaged due to folding.

Second, since the tip of the output side of the fiber base conductor is formed at an acute angle, it may be easily damaged. In particular, damage may easily take place as the laser beam irradiating fiber is led into the lumina of viscera via the endoscope. As damage takes place for the acute-angle portion of the tip of the output side of the fiber base conductor, partial peeling of the reflective coating layer formed on the reflective surface may take place, and burning of the peeled portion may occur.

Also, the acute-angle portion of the fiber base conductor may easily scratch the inner wall of the luminal organ. This is very dangerous.

Purpose of the invention

The purpose of this invention is to solve the aforementioned problems of the conventional methods by providing a type of laser

beam side irradiating fiber characterized by the fact that it has a highly reflective output end without the formation of a reflective coating layer on the laser beam reflective surface, and it is not damaged by burning.

Another purpose of the invention is to provide a type of laser beam side irradiating fiber characterized by the fact that the output end of the laser beam does not scratch the inner wall of the luminal organ.

Summary of the invention

According to this invention, the output end of the laser beam side irradiating fiber is formed as an inclined surface at about 45° with respect to the central axis of the fiber base conductor, and it is fitted with a transparent cylinder with one end closed and not in the form of an acute angle; an air layer is formed on the back of the inclined output surface of the fiber base conductor. Consequently, a high reflectivity can be realized without forming a reflective coating layer on the inclined surface, and it is thus possible to prevent damage by burning of the output end of the fiber and scratching of the inner wall of the luminal organ.

Application examples

In the following, this invention will be explained in more detail with reference to an application example illustrated by annexed figures.

Figure 1 is a cross-sectional view of an application example of the laser beam side irradiating fiber of this invention. Figure 2 is a cross-sectional view cut along line II-II in Figure 1. Fiber base conductor (11) is a conventional optical fiber base conductor made of glass or plastic, with a configuration made of a core and a cladding having different refractive indexes. In this application example, the fiber base conductor is a fused silica fiber with a core size of 400 μm and with an outer diameter of the cladding layer of 650 μm. Over the entire length of fiber base conductor (11), a primary coating layer (12) is formed. Fiber base conductor (11) with said primary coating layer (12) formed on it is further protected by a flexible protective coating tube (13) which can prevent cracks on fiber base conductor (11) or damage by folding of fiber base conductor (11). Said protective coating tube (13) is preferably made of a vinyl resin material, nylon, teflon, or another synthetic resin material. In order to bend the laser beam at a right angle to the length of the fiber in which the laser beam is transmitted, the end portion of fiber base conductor (11) is polished to an optically smooth surface (14) inclined at about 45° to the central axis of fiber base conductor (11). For fiber base conductor (11) with its tip formed at an inclined surface (14) at 45°, a portion containing the tip has primary coating layer (12) and protective coating tube (13) peeled off. After peeling of the primary coating layer and protective coating tube (13) from a portion of the fiber, the output face of fiber base conductor (11) is equipped with a transparent cylinder (15) having one end closed in a hemispherical shape and having a circular cross section, with air-tight bonding between them by means of epoxy

type adhesive (16). Within said transparent cylinder (15), an air layer (17) is formed between the inner surface of cylinder (15) and inclined surface (14) of fiber base conductor (11) as ensured by an appropriate setting of inclined surface (14) of fiber base conductor (11). A step portion (17) is formed over the entire periphery of the opening end side of transparent cylinder (15). On this step portion (18) [sic; 17], the tip portion of a feed [sic; reinforcing] tube (19) for protecting and feeding [sic; reinforcing] fiber base conductor (11) over the entire length, made of teflon or other flexible material is fixed by bonding or by heating to enlarge the inner diameter, followed by installation and then cooling and shrinking for fixing. Between the inner periphery of said reinforcing tube (19) and protective coating tube (13) of fiber base conductor (11), a gap (20) with a circular annular cross section is formed over the entire length. For this purpose, it has appropriate inner diameter and a shape almost identical to the shape of transparent cylinder (15).

For a portion of transparent cylinder (15), when the tip of fiber base conductor (11) and the tip of reinforcing tube (19) are fitted, a groove (20) connected to said gap (21) is formed.

For the laser beam side irradiating fiber with the aforementioned configuration, the laser beam transmitted through fiber base conductor (11) is totally reflected from the inclined surface at about 45° and in contact with an air layer (17). The optical path is bent at a right angle and exits from the side surface of transparent cylinder (15). At the same time, pressurized air is fed into gap (21) set to cover the entire outer circumference of fiber base conductor (11), it is then

ejected to the outside through groove (20) formed in transparent cylinder (15) connected to said gap (21). In this way, a portion of transparent cylinder (15), that is, the peripheral portion including the laser beam output portion, can be cooled, and overheating can be prevented.

In the aforementioned application example, for the laser beam side irradiating fiber, in order to reflect the laser beam transmitted in the fiber base conductor by about 90° so that the laser beam exits to the side with respect to the direction of the field of view of the endoscope, the reflective surface is formed as a total reflection surface on the tip portion of the fiber base conductor with an air layer formed adjacent to the reflective surface equipped with a transparent cylinder with one end closed. Consequently, there is no need to form a reflective layer as in the conventional method, and the various disadvantages caused by the reflective coating layer in the conventional laser beam irradiating fiber can be avoided.

On the other hand, in order to form a total reflection surface of the tip of the output side of the fiber base conductor, an air layer is formed adjacent to the reflective surface by fitting the tip portion of the fiber base conductor with a transparent cylinder with one end closed to a nearly hemispherical shape. It is thus highly resistant to damage, and there is no danger of scratching of the inner wall of the luminal organ by the fiber.

In the aforementioned application example, the transparent cylinder may be made of various types of materials, such as plastics, glass, ceramics, etc., as long as the material used can meet the requirements of transmissivity, refractive index, and

other desired optical characteristics. In particular, it is preferred that materials in which the accumulation of foreign substances is inhibited with high heat resistance be used. Or, a coating may be formed on the outer periphery so as to improve the application performance.

Effects of the invention

As explained in the above, for the laser beam side irradiating fiber of this invention, the end portion of the fiber base conductor is equipped with a transparent cylinder with one end closed; this transparent cylinder is used to seal off the inclined surface of the fiber base conductor. Consequently, the laser beam can be led into the lumina of viscera via endoscope, and can irradiate the lesion portion at normal incidence. In addition, as the aforementioned inclined surface is sealed off by the transparent cylinder, accumulation of foreign substances on the inclined surface can be reliably prevented. In addition, since the cylinder is transparent, the state of the overall inclined surface of the fiber base conductor can be observed from the outside. Consequently, the safety of the inclined surface of the fiber base conductor can be easily confirmed.

Brief explanation of the figures

Figure 1 is a cross-sectional view of an application example of the laser beam side irradiating fiber of this invention. Figure 2 is a cross-sectional view cut along II-II in Figure 1.

11, fiber base conductor
12, primary coating layer
13, protective coating tube
14, inclined surface
15, transparent cylinder
17, air layer
19, reinforcing tube
20, ejecting opening
21, gap

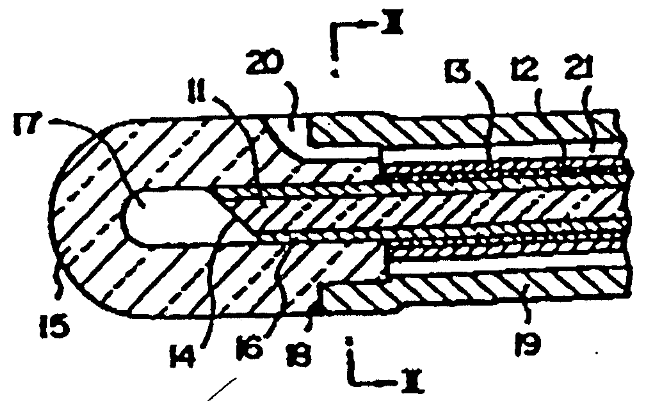

Figure 1.

epoxy

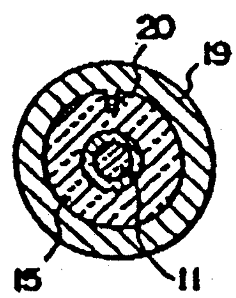

Figure 2.

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